

# Iowa Board of Pharmacy

Frequently Asked Questions: COVID-19

Last update: March 23, 2020

The lowa Board of Pharmacy is committed to protecting the health and safety of lowans during the current COVID-19 pandemic. The Board and staff have received many questions relating to the pandemic and its effect on the provision of pharmacy services in Iowa. On March 22, 2020, Governor Kim Reynolds issued a <u>Proclamation of Disaster Emergency</u> in which she temporarily suspended a number of rules relating to licensing issues with the goal of increasing the availability of health care providers in the practice of pharmacy. In addition to the Governor's Proclamation, the Board published its Statement on Board Enforcement during the COVID-19 Pandemic to provide the Board's intention of exercising risk-based enforcement discretion as it relates to rules that apply to the practice of pharmacy, with the exception of rules relating to controlled substances.

This document intends to provide information and answers to specific questions that the Board has received or anticipates receiving. These FAQs are being provided to all licensees and registrants. This information can also be found on the Board's website at <a href="mailto:pharmacy.iowa.gov">pharmacy.iowa.gov</a> on the home page under the "Health Resources and Links" section. Please note that the Board cannot anticipate every scenario that might occur as it relates to adjusting pharmacy operations as a result of COVID-19 and the challenges that the novel coronavirus may present. The Board anticipates pharmacists will exercise prudent professional judgment in determining how best to modify practice to provide quality pharmaceutical care to lowans while protecting the public and pharmacy personnel.

Additional questions that are not addressed in this document may be directed to <u>Board Compliance Staff</u>. Staff will make every effort to provide a timely response.

The COVID-19 pandemic continues to evolve. The Board anticipates continued submission of additional questions. As such, this document will be updated as additional information warrants. Please continue to check the Board's website for updated versions.

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- Iowa Department of Public Health
  - o Novel Coronavirus (COVID-19)
  - Isolation Guidance for Essential Services Personnel
  - o <u>Isolation Guidance for Iowans</u>
  - o What is Self Isolation?
- U.S. Centers for Disease Control and Prevention (CDC)
  - o Coronavirus (COVID-19)
  - o Coronavirus Disease 2019 (COVID-19) Hospital Preparedness Assessment Tool

- Interim US Guidance for Risk Assessment and Public Health Management of Healthcare Practitioners with Potential Exposure in Health Care Setting to Patients with Coronavirus Disease 2019 (COVID-19)
- Critical Point
  - Critical Point Peer Network
- National Center for Biotechnology Information, US National Library of Medicine
  - WHO Guidelines on Hand Hygiene in Health Care (hand sanitizer formulation)
- United States Pharmacopeia (USP)
  - Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic
  - USP Response to Shortages of Garb and Personal Protective Equipment (PPE) for Sterile Compounding During COVID-19 Pandemic
- United States Drug Enforcement Administration (DEA)
  - o COVID-19 Information Page

## **OPERATING OR CLOSING PHARMACIES**

Question: Can our pharmacy adjust our hours of operation?

<u>Answer</u>: Yes. The Board's rules do not mandate that your pharmacy be open a minimum number of hours or days. It is highly recommended that you provide updated information as far in advance and to the extent possible to your patients. For a telepharmacy operation, the hours of operation of the telepharmacy site are required to be in the agreement with the managing pharmacy, so the sites are encouraged to be in communication with each other and patients to modify hours of operation.

#### Question: Can our pharmacy convert to a closed-door or delivery-only operation temporarily?

<u>Answer</u>: Yes. The Board's rules do not require a general pharmacy license to be open to the public. The pharmacy is encouraged to provide advanced notice, to the extent possible, to the pharmacy's patients and prescribers, as well as signage on the pharmacy exterior to provide information to customers.

# Question: What are the Board's expectations if a pharmacy has to close entirely?

Answer: If a pharmacy is going to close entirely:

- The pharmacist-in-charge or owner should notify <u>Board staff</u> prior to the closing, or as soon as possible after closing (if prior notification is not reasonably possible).
- Patients should be notified prior to the closing, or as soon as possible after closing (if prior notification is not reasonably possible). The notification should provide information about how patients can have their prescription(s) transferred or instruct that they will need to obtain new prescriptions from their provider to be filled at a different pharmacy.
- Clinics, hospitals, and prescribing practitioners from which the pharmacy receives prescriptions should be notified to the extent reasonably possible.
- If the pharmacy plans to reopen at a later date, the above notifications should include the anticipated reopening date.

# Question: Does the Board have recommendations for pharmacies that continue operating?

<u>Answer</u>: In addition to the recommendations elsewhere in this document, pharmacies should consider the following actions when staff are working in a pharmacy that remains open to the public:

- Encourage customers to buy over-the-counter medications (without hoarding) and to refill
  prescriptions before they become exposed to or infected with COVID-19 (keeping in mind
  that individuals do not always know if they have been exposed or infected).
- Establish a process for reducing or eliminating the amount of time customers wait in line to pick up filled prescriptions especially those who are at most risk. Suggestions include:
  - Maximize (or require) use of drive-through window(s) or implement curbside pick up options
  - Initiate an appointment process for prescription pick up
  - o Limit the number of patients that can be in the pharmacy area at one time
  - Initiate prescription delivery services (note that prescription delivery is a task that does not require Board registration)
- Implement infection control procedures:
  - When possible, staff should maintain a distance of 6 feet from patients or other staff members; some pharmacies have placed tape on the floor in 6-foot increments to distance customers from each other
  - Require patient mask use if observed to be symptomatic
  - Regularly clean and disinfect counters, waiting areas, and other spaces especially where public interaction occurs.
  - Place alcohol-based hand sanitizer with at least 60% isopropyl alcohol or ethyl alcohol next to the cash register or check-out area so people can sanitize their hands after using common items, like pens.
  - Staff should wash hands with soap and warm water frequently and for at least 20 seconds. (You can download and print: IDPH Hand Washing Sign)
  - Staff should avoid touching eyes, nose, and mouth.
  - Staff should cover coughs and sneezes with a tissue and discard.
  - Regularly monitor all staff for illness. Staff members should stay home if they have symptoms of any respiratory infection.
  - Some businesses have put in place temporary barriers to limit transmission when customer distance cannot be at least 6 feet, such as plexiglass barriers and hanging clear plastic shower liners
  - Consider limiting the number of patrons allowed in the store at any given time
- Identify staffing contingency plans sooner than later to identify temporary staff that could be called to work in the event existing staff is unavailable due to illness
  - Note that an individual tasked with prescription delivery alone is not required to be registered with the Board.
- Ensure pharmacy policies and procedures are current and readily available should temporary personnel be utilized and current staff is not available to provide needed information.

Question: Can an out-of-state pharmacy which is NOT licensed in Iowa ship prescriptions to patients located in Iowa without obtaining a license?

<u>Answer</u>: At this time, no. A pharmacy intending to ship prescriptions to Iowans in this state must continue to hold an Iowa pharmacy license.

Question: Can an out-of-state wholesaler or drug distributor which is NOT licensed in Iowa ship prescription drug products into Iowa?

Answer: At this time, no. A distributor intending to distribute drug products into this state must hold an appropriate license. A manufacturer must hold a Limited Distributor license while a wholesaler (if it meets the federal definition of a wholesaler) must hold a Wholesale Distributor license. Under the Board's current position to exercise risk-based enforcement discretion, it is possible the board would consider expedited licensure to an applicant which may not meet all the Board's requirements identified in rule (e.g., VAWD accreditation), but at this time the Board has not been made aware of any particular supply issues that would warrant such extreme action. The Board is acutely concerned about the potential for black or gray market operations which may be engaged in the distribution of counterfeit drug products and will take all necessary actions to avoid those operations in lowa.

## PRESCRIPTION DELIVERY

Question: Our pharmacy provides a home delivery service. Our drivers may be exposed to COVID-19 if they have to enter a home to get someone to sign for the delivery of the prescription. Do we have to get the signature?

<u>Answer</u>: No. The Board's rules do not require a patient's signature at delivery. The pharmacy may need to inquire with the patient's third-party payer to determine signature requirements and, if there are, if the payer will temporarily relax the requirement. The lowa Pharmacy Association may also have additional information as it relates to insurer issues during this pandemic. Visit <u>lowa Pharmacy Association's website</u> for more information. Additional information relating to Medicare and CMS actions can be found at <u>CMS Newsroom</u>.

Question: Our pharmacy sometimes delivers filled prescriptions to the workplace of the patient or to a caregiver's workplace. Do the filled prescriptions have to be delivered directly to the patient or caregiver, or can they be dropped off at a central location, like a reception desk?

<u>Answer</u>: The Board voted at its last public meeting to adopt an amendment to 657 IAC 8.15 for delivery of prescriptions. The amended rule, not yet published or effective, will become:

**657—8.15(155A) Delivery of prescription drugs and devices.** A prescription order may be delivered to a patient at any location licensed as a pharmacy. Alternatively, a pharmacy may use the mail, a common carrier, or personal delivery to deliver a prescription order to any location requested by the patient. A pharmacy that delivers prescription orders by one or more alternate methods shall have policies and procedures to ensure patient confidentiality, prescription order

accountability, and proper storage of prescription orders during delivery. When counseling is required pursuant to rule 657—6.14(155A), oral counseling shall be provided before the prescription order is delivered to the patient. Documentation of the delivery of prescription orders shall be maintained by the pharmacy for at least two years from the date of delivery. The term "patient" includes the patient and the patient's authorized representatives.

As such, pharmacies may implement procedures now as allowed by the amended rule to provide prescription delivery services to patients as they request, ensuring patient confidentiality, accountability, and proper storage of the medication(s).

Question: Our pharmacy delivers filled prescriptions to patients who reside in assisted-living facilities. Some of those facilities have asked that deliveries be dropped off at a central location, staffed by a registered nurse or licensed practical nurse. Can we do that?

<u>Answer</u>: Yes. Under the Board's recently adopted amendment to 657 IAC 8.15 (see previous question for text of amended rule) for prescription delivery, the pharmacy can deliver a patient's prescription to any location of the patient's choice, as long as the pharmacy can ensure patient confidentiality, accountability, and proper storage of the medication(s).

Question: My local school nurse has student medications that need to be returned to students who cannot return to school to pick up their medication. Can my pharmacy receive these medications back?

<u>Answer</u>: Yes. If the patient or caregiver cannot get to the school to pick up their medication, the medication can be taken back to the pharmacy *which originally dispensed it* (either the nurse bringing it to the pharmacy or the pharmacy arranging to pick up the medication from the school). The pharmacy can then hold the medication in their will-call area for the patient to come pick up the medication or the pharmacy may deliver the medication to the patient/caregiver.

# PHARMACY PRACTICE (Prescription limitations, Patient Counseling, Substitution)

Question: We have a patient who is out of refills for a medication. We have been unable to get a response from the patient's prescriber. Can we refill the prescription without authorization?

<u>Answer</u>: Unless it's a controlled substance, yes. <u>lowa Code section 155A.29</u> currently authorizes pharmacists to exercise professional judgment by refilling a prescription one time without prescriber authorization if all of the following are true:

- a. The pharmacist is unable to contact the prescriber after reasonable effort.
- b. Failure to refill the prescription might result in an interruption of therapeutic regimen or create patient suffering.
- c. The pharmacist informs the patient or the patient's representative at the time of dispensing, and the practitioner at the earliest convenience, that prescriber reauthorization is required.

<u>Answer</u>: If it's a controlled substance, federal regulation has not been amended or lifted, to date, to allow renewal of a controlled substance prescription without prescriber authorization.

Question: A patient has come to my pharmacy to get a prescription filled because the patient's regular pharmacy has closed indefinitely. My staff has also been unable to contact the prescriber due to their clinic being closed. Can I fill the prescription without getting the required transfer or new prescription from the prescriber?

<u>Answer</u>: Unless it's a controlled substance, yes. <u>lowa Code section 155A.29</u> currently authorizes pharmacists to exercise professional judgment by refilling a prescription one time without prescriber authorization if all of the following are true:

- a. The pharmacist is unable to contact the prescriber after reasonable effort.
- b. Failure to refill the prescription might result in an interruption of therapeutic regimen or create patient suffering.
- c. The pharmacist informs the patient or the patient's representative at the time of dispensing, and the practitioner at the earliest convenience, that prescriber reauthorization is required.

Question: Can my pharmacy set up a "curbside delivery" service, with patients being asked to drop off written prescriptions and pick up their filled prescriptions outside of the pharmacy building?

<u>Answer</u>: Yes. The pharmacy needs to ensure the adjusted procedures ensure patient confidentiality, accountability, and proper storage of medication(s). If a patient requires counseling and the counseling was not provided in advance of the patient picking up the medication (preferable), staff working the "curbside delivery" location must gather from the patient a phone number at which the patient may be contacted for the pharmacist to call to provide counseling.

# Question: Can our pharmacy discontinue provision of face-to-face counseling?

<u>Answer</u>: Yes, as long as the pharmacy has some equivalent method to provide the needed information to the patient. Governor Kim Reynolds' March 17, 2020, State of Public Health Disaster Emergency includes provisions to expand patient interactions with health care practitioners via telecommunications. While the Board strongly believes that patient safety is best protected by a pharmacist counseling a patient about their medication *before* it is delivered or dispensed to a patient, the pharmacy can certainly adjust processes to conduct such counseling in an alternate manner, such as via telephone.

Question: Is a pharmacist authorized to engage in therapeutic interchange of a medication when or if the prescribed medication is not available, without contacting the prescribing physician for authorization?

<u>Answer</u>: No. <u>lowa Code section 155A.32</u> authorizes drug product selection but the authorization is limited to generic substitution without prescriber authorization.

Question: My CPR certification is due to expire soon and the training organization has indefinitely suspended all in-person training. Will I have to discontinue administering immunizations until I can complete certification?

Answer: No. The Board recognizes that many in-person events have been cancelled or postponed indefinitely and believes that the public safety is still best protected in ensuring access to vaccinations. If there are other immunizing personnel in the pharmacy available to administer vaccinations, have those individuals perform that task. If you are the only immunizer available, you are encouraged to complete an online, didactic program to at least receive refresher information, but it will not be viewed as an acceptable substitute for the hands-on training obtained during a CPR certification program for healthcare providers. The Board will exercise enforcement discretion for those pharmacists who are unable to renew CPR certification during this emergency situation.

Question: Is my pharmacy allowed to skip the signature requirement for over-the-counter sales of pseudoephedrine or over-the-counter dispensing of schedule V cough syrups?

<u>Answer</u>: At this time, no. The Board is not intending to exercise enforcement discretion relating to any rule which applies to controlled substances.

Question: How do I handle prescriptions which are subject to REMS laboratory testing?

<u>Answer</u>: Please review <u>Coronavirus (COVID-19) Update: FDA provides update on patient access to certain REMS drugs during COVID-19 public health emergency for guidance.</u>

Question: Should pharmacists continue to provide routine immunizations during the COVID-19 pandemic?

Answer: The CDC published a general answer to this question:

# Q: Should any diagnostic or therapeutic interventions be withheld due to concerns about transmission of COVID-19?

A: Patients should receive any interventions they would normally receive as standard of care. Patients with suspected or confirmed COVID-19 should be asked to wear a surgical mask as soon as they are identified and be evaluated in a private room with the door closed. Healthcare personnel entering the room should use <u>Standard and Transmission-based Precautions</u>.

Continued influenza immunizations have the potential to result in fewer patients that have influenza symptoms that could be confused for those of COVID-19. This has the potential to reduce the number of patients seeking advice from the healthcare system, potentially requesting COVID-19 tests that will result as negative. This is equally true for other routine immunizations; anything that can contribute to fewer patient visits to prescriber offices and hospitals will allow those entities to triage patients with coronavirus exposure symptoms and care for those patients with advanced COVID-19.

The Board encourages pharmacists to continue to provide routine immunizations if practitioners feel comfortable and those procedures can be performed according to the CDC Infection

<u>Prevention and Control Recommendations for Patients Suspected or Confirmed Coronavirus</u> <u>Disease 2019 (COVID-19) in Healthcare Setting Guidelines.</u>

Please pay attention to these details:

- Limit how germs enter your facility
  - If patients have respiratory symptoms, please direct them to their healthcare provider.
  - Only the patient receiving the immunization should be present with staff in the procedure room. Extra people should be minimized to the extent possible.
  - Ensure staff is familiar with recommended hand hygiene procedures; staff must perform these procedures before and after patient contact.
  - Ensure staff self-isolate if they have symptoms or have been exposed to people with COVID-19 symptoms. Staff that meet these criteria must not perform immunization procedures.
- Staff should wear required Personal Protective Equipment (PPE) since recommended physical distancing cannot be employed, which includes:
  - Gloves
  - Gowns
  - Respirator or mask
- Staff should disinfect the procedure areas immediately after finishing immunization administration.

# **REMOTE PROCESSING**

Question: Will the Board allow pharmacists and technicians to work remotely from home in order to complete duties that would normally have to occur within a licensed pharmacy?

Answer: Yes. The pharmacy needs to be able to ensure confidentiality of patient files at the remote location, security of the computer system and internet connection (preferably encrypted), and that all work performed by a technician is reviewed by a pharmacist. As it relates to tasks involving product verification, the computer hardware and software must be adequate for the task being performed, such as using two-way, real-time audiovisual connection (not just audio connection).

Question: Can pharmacists and technicians working in a pharmacy be remotely involved in the dispensing process of another pharmacy?

<u>Answer</u>: Yes, as long as the pharmacies involved have the appropriate hardware and software to exchange the necessary data to safely and securely perform the tasks and that work completed by technicians that would otherwise be verified by a pharmacist continues to be verified by a pharmacist.

#### PHARMACY SERVICES FOR LONG-TERM CARE FACILITIES

Question: Can our pharmacy delegate stocking an automated dispensing machine used for emergency doses to a facility nurse if the facility has restricted access to the facility?

Answer: Yes, if the automated dispensing machine has barcode-scanning capability.

# PHARMACIST-TECHNICIAN / PHARMACIST-INTERN RATIOS

Question: Will the Board allow pharmacies to exceed the pharmacist-technician ratio (in technician product verification programs) or pharmacist-pharmacist intern ratio?

<u>Answer</u>: Yes, but only if the purpose in doing so is necessary due to an actual impact of the COVID-19 virus on the pharmacy, facility, or staff involved. Pharmacists should continue to be diligent in their supervision of pharmacist-interns to ensure proper information is provided to patients and accurate work is being completed.

#### PHARMACY PERSONNEL / LICENSING ISSUES

Question: Can I continue to have a technician trainee working in the pharmacy if their trainee registration is due to expire soon but their CPhT national exam has been postponed due to COVID-19?

<u>Answer</u>: Yes. The Governor's March 22 Proclamation temporarily suspends the rule which would prohibit a technician trainee from practicing as a technician following the expiration of the trainee's one-year registration unless the technician has obtained national certification. The Proclamation allows a technician trainee whose registration expires between March 22 and May 31, and who is unable to sit for the examination, to continue to practice as a technician while the registration is expired. The Board will continue to monitor the situation with testing sites and will exercise enforcement discretion if necessary following the expiration of the Governor's waiver.

Question: What if pharmacy personnel have no child-care options? Can pharmacy personnel bring their child(ren) into the pharmacy while they work?

<u>Answer</u>: The Board certainly understands this could become a reality as schools have been closed across the state. The Board would be inclined to exercise enforcement discretion if the pharmacy can ensure patient confidentiality, security from unauthorized access to prescription drugs (including and especially controlled substances), and general quality patient care.

Question: If my pharmacy needs to hire new pharmacy technicians and pharmacy support persons which are intended to be temporary positions to get through the emergency period, do we still need to register them with the Board?

<u>Answer</u>: The Board's existing rule is to obtain registration within 30 days of employment. Although the Board office is closed to public visitors, Board staff is currently continuing regular operations.

Applications may be submitted via regular mail or brought to the Board office and deposited into the drop box in the front vestibule. Licensing staff will continue to process applications as normal and the Board will exercise enforcement discretion in situations where the application has been received but not processed within the required timeframe. Keep in mind that some tasks that may be ramped up during this time <u>do not require registration</u> with the Board, such as delivery.

Question: Can the pharmacy utilize store employees who are not currently registered with the Board in any capacity to assist with duties normally handled by registered pharmacy support persons, such as entering the pharmacy to assist with handling payment transactions for prescriptions?

<u>Answer</u>: During this emergency period, the Board will exercise enforcement discretion in situations where, expressly due to personnel impacts resulting from COVID-19, a pharmacy allows an unregistered employee to assist with pharmacy support person tasks.

Question: Can a pharmacist that is licensed and in good standing in another state perform work inside lowa or remotely from another state?

<u>Answer (non-IA-licensed RPh working in out-of-state pharmacy)</u>: Pharmacists who work in an lowa-licensed non-resident pharmacy may provide pharmacist services for lowa patients without specifically holding an lowa pharmacist license.

Answer (non-IA-licensed RPh working in lowa pharmacy): Governor Reynolds' March 22 Proclamation allows an lowa pharmacist whose license is inactive or lapsed (for no more than 5 years) to return to the practice of pharmacy through the emergency period (March 22 through April 16). The Board will be issuing additional guidance in the coming days related to this part of the Governor's Proclamation. The allowance does not extend to pharmacist licenses which were voluntarily surrendered or revoked. Otherwise, <a href="Lowa Code section 155A.7">Lowa Code section 155A.7</a> requires a pharmacist to hold an lowa pharmacist license in order to practice, so the Board cannot authorize a pharmacist to practice pharmacy who is not currently licensed or who holds an inactive or lapsed license.

Question: The Governor's March 22 Proclamation relaxes the continuing education requirements for license renewal. Will this apply to my pharmacist license renewal this year?

<u>Answer</u>: The Board is currently reviewing this aspect of the Governor's Proclamation and will be issuing further guidance in the coming days.

Question: The Governor's March 22 Proclamation relaxes the rules relating to license and registration renewals. How long will that be effective and can I still practice if I haven't renewed my license or registration?

<u>Answer</u>: The suspension applies to licenses and registrations which expire between March 22 and April 16 only. The Board of Pharmacy is operational at this time and licensing staff is continuing to process license and registration renewals. The Board has no expectation at this time that applications will not be processed as normal. Licensees and registrants are encouraged to utilize the Board's online renewal process (more information can be found <a href="here">here</a>). Licensees and

registrants who are unable to renew and whose license or registration expires between March 22 and April 16 are authorized to continue practice until they are able to submit for renewal. The Board will be issuing further guidance relating to this in the coming days.

Question: The Governor's March 22 Proclamation relaxes the rules relating to the completion of clinical, practical, or internship experience for licensure. How long will that be in effect?

<u>Answer</u>: The Governor's Proclamation is valid between March 22 and April 16, 2020. Iowalicensed pharmacist-interns who are currently completing or who are scheduled to complete their experiential program to qualify for graduation this spring and are unable to complete the college-based clinical program, due solely to the COVID-19 pandemic, will continue to be eligible for pharmacist licensure in Iowa if all other requirements are met. The Board will be issuing additional guidance in the coming days relating to this aspect of the Governor's Proclamation.

Question: The Governor's March 22 Proclamation relaxes the rules relating to the completion of background checks for professional licensure. How long will that be in effect?

<u>Answer</u>: The Governor's Proclamation is effective between March 22 and April 16. The Board will be issuing additional guidance in the coming days relating to this aspect of the Governor's Proclamation.

Question: I've heard that a pharmacist whose license has expired would be able to come back to work during this pandemic. Is that true?

<u>Answer</u>: Yes, with some conditions. The Governor's March 22 Proclamation relaxes the rules which would otherwise prohibit a pharmacist from practicing with an expired or lapsed license. A pharmacist whose license has been inactive or lapsed for less than 5 years may return to work as a pharmacist in lowa. The Governor's action does not appear to apply to pharmacists whose license has been voluntarily surrendered or revoked. The Governor's action also does not allow a pharmacist licensed in another state to practice pharmacy in lowa without an lowa pharmacist license.

Question: I'm a pharmacist licensure applicant and have successfully completed one of the two required exams to qualify for licensure, but the testing centers have closed and I cannot take the second exam at this time. Will I lose credit for the first exam I have taken if I reach/exceed the one year requirement for passing both components?

<u>Answer</u>: No, you will not lose credit. The Governor's March 22 Proclamation relaxes the rule which requires both exam components to be completed within one year of passing the first exam. The Board will be issuing further guidance in the coming days relating to this aspect of the Governor's Proclamation.

# PHARMACIST SCOPE OF PRACTICE and PROTOCOLS

Question: Will the Board be temporarily expanding the scope of practice for pharmacists so that they can perform functions like conducting COVID-19 or rapid strep tests with subsequent prescribing of appropriate antibiotics?

<u>Answer</u>: Not at this time. The authority to allow pharmacists to engage in such testing and prescribing comes solely from the lowa Legislature. Under existing law, pharmacists are authorized to practice under a collaborative practice agreement with a practitioner to engage in patient care activities. Under Board rules, the collaborative practice agreement would typically only apply to patients of the practitioner who has authorized the agreement. The Board would take enforcement discretion in situations where a practitioner has authorized any pharmacist subject to the collaborative practice agreement to engage in the authorized pharmacist services for patients other than the authorizing practitioner.

Question: If a vaccine is approved by FDA and available for administration to prevent the novel coronavirus, will pharmacists be authorized to administer the vaccine under a physician-signed immunization protocol or the Board's statewide protocol?

<u>Answer</u>: Yes. When a vaccine is approved by FDA and added to the ACIP recommendation guidelines, a pharmacist is authorized to administer the vaccine to a patient pursuant to the Board's statewide protocol for immunizations. Under the Board's statewide protocol, a pharmacist is authorized to administer to patient's six months of age and older "other immunizations in response to a public health emergency." If the state's public health emergency has expired or been lifted at the time a vaccine becomes eligible for administration, a pharmacist would only be authorized to administer the vaccine to patients aged 18 or older.

The Iowa Code provision which authorizes immunization administration by pharmacists under a physician-signed protocol sunsets on June 30, 2020, so it is unlikely that a vaccine will be FDA-approved and identified in ACIP recommendations by then. If a vaccine is eligible for administration by then, the physician-signed protocol would need to be updated to reflect the vaccine authorization.

#### HOARDING OF DRUGS / SUPPLY CHAIN ISSUES

Question: Are we authorized to limit sales of over-the-counter medications and supplies, such as acetaminophen, ibuprofen, cough medicine, etc.?

<u>Answer</u>: Yes. The Board has no mandate that the pharmacy sell these products, so it is entirely a business decision for the pharmacy to set purchase limitations if desired.

Question: Can I dispense more than the authorized quantity of a prescription, if refills are available?

<u>Answer</u>: Unless it is a controlled substance, yes. <u>lowa Code section 155A.27</u>, <u>subsection 6</u>, authorizes a pharmacist to dispense "up to the total number of dosage units authorized by the prescriber on the original prescription and any refills of the prescription, not to exceed a 90-day supply." It is recommended, however, that pharmacists exercise professional judgment in making determinations on dispensing additional quantities of prescription drugs. While it is beneficial to limit the number of pharmacy visits for patients, there is also a concern about adding to the strain of the drug supply chain.

Question: Am I authorized to limit a quantity dispensed on a prescription if I am concerned about drug supply chain issues?

<u>Answer</u>: Yes, you can use your professional judgment to dispense partial quantities of prescription medications in order to prevent the situation of limited drug supplies.

Question: How should my pharmacy handle prescriptions being issued for large quantities of hydroxychloroquine or chloroquine?

<u>Answer</u>: The Board encourages you to use your best professional judgment in determining the legitimacy of these prescriptions and the likely intent. For an example of what action other states are taking: the Idaho Board of Pharmacy issued an emergency rule that limits new prescriptions to a quantity of a 14 day supply along with a diagnosis code or documented positive COVID-19 test, unless the patient was previously established on the drug.

#### **COMPOUNDING**

Question: Does the Board have any recommendations concerning the possibility of shortages of garb and personal protective equipment (PPE)?

Answer: Yes. The Board issued guidance relating to this on March 9, 2020, which can be found here.

The Board strongly encourages compounding personnel to utilize the resources available at the <u>Critical Point Peer Network</u> where you can sign up for a Silver Subscription at no charge and access valuable information relating to compounding challenges resulting from the COVID-19 pandemic.

Additionally, USP issued an information resource that might be helpful: <u>USP Response to Shortages of Garb and Personal Protective Equipment (PPE) for Sterile Compounding During COVID-19 Pandemic</u>. The Board is aware that the recommendations are slightly different from those provided by Critical Point. The Board is supportive of licensees making professional judgments in their individual situation to determine the best course of action to ensure product quality, public safety, and employee protection.

Question: Is it ok for my pharmacy to delay routine media-fill testing, gloved fingertip testing, and garbing technique observation in an effort to conserve garb?

<u>Answer</u>: Maybe. Since media-fill testing can reasonably be completed at the end of a compounding shift, this would not require additional, unnecessary use of garb and should not be delayed. If garbing is simply for the purpose of observing the garbing and aseptic technique of compounding personnel (unless for a newly trained compounder), the observer may consider remote observation (through a window, etc.) during normal compounding operations or, if that's not reasonable, testing could be delayed.

Question: Can my pharmacy compound prescription medications that are essentially copies of FDA-approved, commercially available products if they are on backorder or not available?

<u>Answer</u>: Yes. Board rule <u>657 IAC 20.12</u> currently authorizes a pharmacist to compound a drug that is otherwise commercially available when that product is not available due to a documented drug shortage or the drug is listed on the <u>FDA Drug Shortages List</u>.

Question: Given shortages of hand sanitizer, can pharmacies, manufacturers, and outsourcing facilities compound and sell hand sanitizer products?

Answer: Yes. Board rules would ordinarily limit a pharmacy to dispensing compounded products only pursuant to a patient-specific prescription, but FDA recently published its <a href="Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency">Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency</a> encouraging pharmacies to engage in such compounding. The Board will exercise enforcement discretion when pharmacies and outsourcing facilities engage in compounding of hand sanitizer in compliance with FDA guidance. Additionally, USP issued an informational resource which might be helpful: <a href="Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic">Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic</a>.

The Board has been alerted that PCCA has a formulation that is slightly different than the FDA guidance identifies. The Board is supportive of a pharmacy using a formulation by any nationally recognized compounding authority (FDA, PCCA, etc.) as long as the pharmacy or outsourcing facility is limiting the BUD to 30 days as recommended by WHO and USP.

As it relates to manufacturers who do not already have FDA approval to produce these products, FDA released *temporary* <u>Guidance for Industry: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)</u>. The Board will also exercise enforcement discretion with manufacturers which are producing hand sanitizers under FDA's Guidance.

Question: I have heard on the news about distilleries beginning to manufacture hand sanitizer. Is this legal?

Answer: At this time, FDA has issued *temporary* <u>Guidance for Industry: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) which establishes that FDA will not take enforcement action against a</u>

firm for this activity if they are strictly following the guidance for formulation, documentation, and controls.

Question: Can my pharmacy implement remote verification of compounding activities?

<u>Answer</u>: Yes, see "<u>REMOTE PROCESSING</u>" section for information about systems requirements to implement product or staging verification during compounding operations.

## TELEHEALTH ENCOUNTERS / PRESCRIPTIONS ISSUED VIA TELEMEDICINE

Question: If an lowa-located health system engages with prescribers located in another state to provide remote telehealth services to lowa patients, is the prescriber required to obtain an lowa CSA registration prior to issuing a controlled substance prescription?

<u>Answer</u>: Temporarily, no. Under Section Nine of the Governor's State of Public Health Disaster Emergency issued March 17, 2020, all implementing regulations establishing preconditions on the provision of telemedicine services have been temporarily suspended. As such, a prescriber would not be required to obtain an Iowa CSA prior to providing telemedicine services, including issuing a controlled substance prescription, to a patient located in Iowa. Once the Governor's declaration has been lifted, the Board's rules would be reinstated to require an Iowa CSA registration prior to issuing a controlled substance prescription via telemedicine to a patient located in Iowa.

<u>DEA</u> has also announced that, as of March 16, 2020, and continuing for as long as the Secretary's designation of a public health emergency remains in effect, DEA-registered practitioners in all areas of the United States may issue prescriptions for all schedule II-V controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following conditions are met:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;
- The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and
- The practitioner is acting in accordance with applicable Federal and State laws.

# **BOARD GENERAL OPERATIONS AND MEETINGS**

Question: Will the Board of Pharmacy offices remain open for business and will the hours of operation remain the same?

<u>Answer</u>: The Board office is currently closed to the public. A mail drop box has been placed in the front vestibule in which items for Board staff may be placed. Licensees and registrants are asked to utilize the Board's <u>Online Services</u> to the extent possible. Questions can be directed to <u>Board Staff</u>. The Board's hours of operation will remain the same at this time.

Question: Will the Board's regularly scheduled meetings (Open session Board meetings, Rules Committee, Prescription Monitoring Program Advisory Council, and Monitoring Program for Pharmacy Professionals) continue to be held?

<u>Answer</u>: At this time, the Board is postponing any in-person meeting that is currently scheduled through the end of March (consistent with Governor Kim Reynolds' State of Public Health Disaster Emergency declaration published March 17, 2020, prohibiting gatherings of 10 or more individuals). As necessary, the Board may hold teleconference meetings to handle the business of the Board. Determinations of public meetings beginning in April will be made at a later date.

Question: Will I be determined to be noncompliant with my IMP3 contract if I am unable to attend meetings or practitioner appointments that are included in my contract?

<u>Answer</u>: Not if you are in routine communication with the IMP3 Case Manager to keep her updated on your situation.

# **BOARD LICENSING OPERATIONS**

Question: Will licensees be allowed to continue operating or practicing if the Board is unable to process renewals?

<u>Answer</u>: Yes. The Board's current rules allow continuation of operations or practice during a 30 day grace period while a renewal application is being processed. Board licensing staff will continue to process applications and the Board does not anticipate any excursion from its normal application processing times. Licensees and registrants are encouraged to utilize the Board's <u>Online Services</u>.

Question: Will licensees and registrants already licensed/registered with the Board be allowed to continue practicing after their license/registration expires as a result of their inability to timely renew their license/registration due to the COVID-19 pandemic?

<u>Answer</u>: Yes, under Governor Reynolds' March 22 Proclamation licensees and registrants who are unable to renew between March 22 and April 16 will be authorized to continue practice. The Board reminds licensees and registrants that renewal is available <u>online</u>, which processes in a matter of minutes, if you have all necessary documentation available. Board staff continues to operate and does not anticipate any delays in processing. The Board will be issuing additional guidance in the coming days relating to this aspect of the Governor's Proclamation.

Question: Will the Board process applications for new licenses and registrations in a normal manner?

<u>Answer</u>: At this time, the Board does not anticipate any excursion from its normal processing, but as COVID-19 continues to present incredible challenges, Board staff may need to make adjustments in the Board's operations accordingly. The Board recognizes that new license/registration applications may be submitted as a means to assist with the pandemic in lowa, so Board staff will make every effort to timely process new applications.

# **BOARD VARIANCE/WAIVER REQUEST REVIEWS**

Question: Will the Board continue to process variance/waiver requests that require Board approval?

Answer: Pursuant to the Board's Statement on Enforcement Discretion issued March 23, 2020, the Board is essentially waiving all non-essential rules relating to the practice of pharmacy with the expectation that all licensees and registrants operate at a minimum standard of care ("standard of care" meaning that which would be provided in a similar setting by a reasonable and prudent licensee or registrant with similar education, training, and experience). As the Board is able to reconvene at a regular open session meeting after the discontinuation of the emergency period, the Board will continue to review any submitted waiver/variance requests previously received (e.g., VAWD accreditation requirements, electronic prescribing mandate, etc.).

Question: If we have submitted a request to extend an existing waiver request but the Board is unable to consider the request due to adjustments in meetings and agendas, can we continue to operate under the expired waiver?

<u>Answer</u>: Yes. It's possible the waiver that had been granted would be subject to the Board's generalized declaration of exercising enforcement discretion in the practice of pharmacy. If the waiver applied to some other rule that somehow would not be covered by the Board's Statement, the licensee may continue to operate under the prior waiver until such time that the Board can meet to consider the renewal request.